Surgiflo Haemostatic Matrix Kit

Procedural steps and scientific information after initial consultation

Application number	Scope	Opinion/ Notification [1] issued on	Summary
IA/0040	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	29/07/2024	To submit a 2nd step notificaiton procedure.
IB/0038	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	17/06/2024	To introduce a new batch of in-house reference material and a qualification protocol for a reference standard.
IB/0037	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	26/03/2024	Changes to the approved stability protocol of the finished product to the pH limit under accelerated conditions.
II/0036/G	This was an application for a group of variations.	14/12/2023	Minor changes in the manufacturing process of the biological finished product;

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.

	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB		Change to the source of fibrinogen used for active substance potency testing; Changes to the manufacturing process of the finished product; Minor changes in the manufacturing process of the finished product; Change to the source of fibrinogen used for finished product potency testing.
IA/0035/G	This was an application for a group of variations. Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	18/09/2023	Deletion of a manufacturing site. Change in a test procedure of the finished product. Change in the test procedure for the immediate packaging of the finished product.
II/0034/G	This was an application for a group of variations. Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II	15/06/2023	To add a supplier of immediate packaging glass vials of the sterile SURGIFLO Haemostatic Matrix Kit. Change in the qualitative composition of the primary packaging of the sterile SURGIFLO Haemostatic Matrix Kit.
II/0033/G	This was an application for a group of variations. Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	25/05/2023	To add a specifications parameter for the active substance human thrombin together with the corresponding method. To add an alternative site responsible for batch control/testing of the finished product Surgiflo; To add an alternative site responsible for manufacture of the active substance human

	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II		thrombin; To add an alternative supplier of the stoppers; To add an alternative site responsible for manufacture of the lyophilized human thrombin finished product.
II/0032/G	This was an application for a group of variations. Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II	12/01/2023	Change in the composition of immediate packaging. To replace a supplier of the glass vials. Furthermore, 6-months stability data is submitted to fulfil the post approval commitment. Finally, the MAH used the opportunity to update the dossier with editorial changes.
IB/0031/G	This was an application for a group of variations. Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	08/12/2022	To change the Notified Body, minor changes to a test procedure for the active substance Human Thrombin and editorial changes.
IB/0029	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	30/04/2021	Change in the test procedure of the active substance and finished product.
IB/0028	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	15/03/2021	Change to in-process tests applied during the manufacture of the finished product.

IB/0027	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	15/03/2021	Change in the manufacturing process of the finished product.
IB/0026	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	05/02/2021	Deletion of a non-significant in-process test applied during the manufacture of the finished product.
II/0022	Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II	28/01/2021	Change in the batch size range of the finished product.
II/0021	Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II	14/01/2021	Change in the batch size range of the finished product.
IA/0025	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	06/01/2021	Replacement of a site for stability testing of the finished product.
IA/0024	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	09/12/2020	Deletion of a manufacturing site for the finished product.
IA/0023	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	09/12/2020	Minor changes to an analytical procedure performed as part of the release tests of the finished product.
IB/0020	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	30/07/2020	Change in the manufacturing process of the finished product.
IB/0019	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	22/04/2020	To add an alternative in-process test method applied during the manufacturing process of the active substance and finished product
IB/0018	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	10/03/2020	Changes to the approved stability protocol of the finished product.

IA/0017	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	15/09/2017	Deletion of manufacturing sites for the finished product.
II/0016	Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II	20/07/2017	To introduce an alternative lyophilizer.
II/0015/G	This was an application for a group of variations. Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	10/11/2016	To add an alternative manufacturing site of the finished product, to increase of the batch size of the finished product and to add a new test procedure to the specification of the finished product.
IB/0013	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	15/06/2016	Minor change in the manufacturing process of the finished product.
IA/0014	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	30/05/2016	Change in the immediate packaging of the finished product.
IB/0012	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	16/12/2015	Other changes to a test procedure (including replacement or addition) for the finished product.
II/0010	Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II	15/10/2015	To extend the shelf-life of the active substance.
IA/0011	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	15/09/2015	Change in the immediate packaging of the finished product.
IA/0009	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	24/06/2015	To delete a non-significant parameter from the specifications of the finished product.

IB/0008	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	23/06/2015	Changes in the manufacturing process of the medical device.
IA/0007	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	17/09/2014	Change in the immediate packaging of the finished product.
II/0005	Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II	25/04/2014	Changes to the manufacturing process of the active substance and finished product.
IA/0006	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	15/04/2014	Minor change in a test procedure for the finished product.
II/0003	Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II	21/11/2013	To add an alternative finished product manufacturing site, to add an alternative batch release testing site for the finished product and change in batch size (including batch size ranges) of the finished product.
IA/0004	B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter	31/10/2013	To delete non-significant specification parameters for the finished product.
IB/0002	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	16/05/2013	Extension of the shelf life of the finished product (as packaged for sale).
IA/0001	B.II.a.3.b.1 - Changes in the composition (excipients) of the finished product - Other excipients - Any minor adjustment of the quantitative composition of the finished product with respect to excipients	26/07/2011	Minor adjustment of the quantitative composition of the finished product with respect to excipients.